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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,243

10/27/2003

Stephen Hamilton

GFI/109 CIP

4492

7590

08/09/2006

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,243	<b>Applicant(s)</b> HAMILTON, STEPHEN	
	<b>Examiner</b> David Guzo	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25,30-46 and 51-53 is/are rejected.
- 7) ☒ Claim(s) 26-29 and 47-50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/20/06;7/20/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

The examiner inadvertently omitted claims 49-51 from the previous Office Action.

These claims will be addressed in this Office Action.

### **35 USC 112, 1<sup>st</sup> Paragraph Rejections**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-25, 30-46 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record and for reasons outlined below.

Applicant traverses this rejection by asserting that they have demonstrated a structure-function relationship with regard to nucleic acids encoding endomannosidase activity. Applicant indicates that the specification provides three examples of nucleic acids encoding endomannosidases and that these species demonstrate that there is a structure/function correlation. With regard to the hybridization language added to the claims, applicant refers to Example 9 of the Written Description Guidelines (hereafter the "Guidelines") for the Examination of Patent Applications and argues that the

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circumstances recited in the instant claims are covered by said example and therefore the invention is described.

Applicant's arguments filed 5/24/06 have been fully considered but they are not persuasive. Initially, with regard to the similarity of Example 9 in the Guidelines to the instant claims, it is noted that Example 9 recites hybridization under "**highly** (emphasis added) stringent conditions" and that hybridization under highly stringent conditions ensures that only structurally similar nucleic acids will hybridize. The example concludes that the combination of species encompassed within the scope of the example claim (as a result of hybridization under highly stringent conditions) combined with the coding function of the DNA and the level of skill in the art are sufficient to provide a description of the claimed genus. The instant case is significantly different from the Example 9 in that applicant only recites hybridization under "stringent conditions". Under the instantly claimed hybridization conditions, nucleic acids with a significantly lesser degree of structural similarity to the recited SEQ ID NOs would hybridize and hence the structural similarity necessary for the description requirement to be satisfied would be lacking. Since the instant circumstances differ factually from the conditions outlined in Example 9 of the Guidelines, said Example cannot be used as a rationale for concluding that the instant claims comply with the written description requirement of 35 USC 112, 1<sup>st</sup> paragraph.

With regard to applicant's arguments that the disclosure of three species of endomannosidase coding regions satisfies the requirement for a structure – function correlation, it is noted that applicant has not provided any evidence as to regions of the

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endomannosidase molecules which are essential for specific functions, no evidence as to regions encoding structural motifs necessary for enzymatic activity, no evidence as to regions encoding enzymatic active sites, etc. The disclosure of three species without any description of the relevant functional motifs of the molecules does not provide the skilled artisan with a description of the claimed genus. Additionally, as the three enzymes are from two related species (mouse and rat) and humans and the genus encompasses any molecule with endomannosidase activity (encompassing millions of different molecules from potentially every organism in the phylum Chordata, it must be concluded that the three disclosed species do not represent a representative number of species sufficient to describe the claimed genus.

### 35 USC 112, 2<sup>nd</sup> Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is dependent upon claim 35 which recites a method for modifying glycosylation structures on glycoproteins in lower eukaryotic host cells; however, claim 39 recites that the endomannosidase is **of host origin**. Since endomannosidase enzymes appear to be limited to organisms in the phylum Chordata, it is unclear how a

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**lower eukaryote host cell** (i.e. yeast, fungi, etc.) can have an endogenous endomannosidase enzyme.

No Claims are allowed.

Claims 26-29 and 47-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
DAVID GUZO  
PRIMARY EXAMINER

David Guzo  
July 30, 2006